

U. S. Department of Energy



Consolidated Audit Program

Module 1 with LIMS and AIHA

Checklist for General Laboratory Practices Quality Assurance Management

**Revision 2
February 17, 2004**

Audit ID:

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.1	Organization and Management		
1.1.1	Is the laboratory legally identifiable? Describe document(s) examined usually found in the QAP. <i>Quality Systems for Analytical Services, 4.1</i>		
1.1.2	The Quality Assurance Plan (QAP) includes an organization chart showing that Quality Assurance personnel: <ul style="list-style-type: none"> • operate independently from line management; • are not directly involved with cost, schedule or production functional areas; and, • report directly to the highest level of laboratory management. <i>Quality Systems for Analytical Services, 4.2 (a, b, c, d); 5.2c</i> <i>(AIHA Laboratory QA Policies, Section 2A.6.2)</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.1.3	<p>General Quality Assurance responsibilities include:</p> <ul style="list-style-type: none"> oversight of corrective actions; oversight of PE analysis; report to management; internal audits; review of SOWs and SOPs; and, procurement quality assurance. <p><i>Quality Systems for Analytical Services, 5.3.1-5.3.5</i> <i>AIHA Laboratory QA Policies, Section 2A.6.2</i></p>		
1.1.4	<p>A Quality Assurance Officer has been designated in writing who is empowered to:</p> <ul style="list-style-type: none"> stop unsatisfactory work; prevent reporting results from an out of control measurement system; initiate and monitor corrective action procedures; and, revise, control and distribute the QAP. <p><i>Quality Systems for Analytical Services, 4.2g(1); 5.1e</i> <i>AIHA Laboratory QA Policies, Section A.6.2</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.1.5	The laboratory organization possesses well-defined and documented roles and responsibilities for each position. <i>Quality Systems for Analytical Services, 4.2d(2)</i> <i>AIHA Laboratory QA Policies, Section 2A.6.6</i>		
1.1.6	The laboratory Quality Control Manager or his/her designee periodically reviews control charts at a specified frequency for out of control conditions and initiates appropriate corrective action procedures. <i>Quality Systems for Analytical Services, 4.2g(1-7)</i> <i>AIHA Laboratory QA Policies, Section 2A.8.10.5</i>		
1.2	Quality System – Establishment, Audits, Essential Quality Controls, and Data Verification		
1.2.1	The laboratory has developed a Laboratory QAP consistent with DOE QSAS that is issued and maintained as a controlled document. <i>Quality Systems for Analytical Services, 5.1a</i>		
1.2.2	The QAP is accessible to all laboratory personnel and they are aware of its location. <i>Quality Systems for Analytical Services, 5.1b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.1</i>		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.2.3	<p>The QAP defines the laboratory's policies and its commitment to:</p> <ul style="list-style-type: none"> • ethical standards; • client confidentiality; • good laboratory practices; and, • client service. <p><i>Quality Systems for Analytical Services, 5.2r; 5.2s; 5.2x</i> <i>AIHA Laboratory QA Policies, Section 2A.8.3</i></p>		
1.2.4	<p>The QAP includes a listing of certifications and accreditations or a reference to the location of such a list if not part of the QAP.</p> <p><i>Quality Systems for Analytical Services, 5.2h</i></p>		
1.2.5	<p>The QAP describes the:</p> <ul style="list-style-type: none"> • organization structure; • functional responsibilities; • levels of authority; and, • interfaces. <p>for those managing, performing and assessing work.</p> <p><i>Quality Systems for Analytical Services, 5.2b, c, and e</i> <i>AIHA Laboratory QA Policies, Section 2A.8.1</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.2.6	<p>The laboratory has established a minimum frequency for review of controlled documents and procedures.</p> <p><i>Quality Systems for Analytical Services, 5.2d</i> <i>AIHA Laboratory QA Policies, Section 2A.8.16</i></p>		
1.2.7	<p>The laboratory maintains a current list of available (on hand) equipment types, models, years and a general description of the facility.</p> <p><i>Quality Systems for Analytical Services, 5.2i, 8.0e</i> <i>AIHA Laboratory QA Policies, Section 2A.5</i></p>		
1.2.8	<p>The laboratory has established an internal audit program which includes:</p> <ul style="list-style-type: none"> • independent assessments by technically qualified personnel; • maintenance of an audit schedule; • audit procedures; • standard formats for reporting findings to laboratory management; and • methods for implementing and verifying corrective actions. <p><i>Quality Systems for Analytical Services, 5.3.1; 5.3.5a</i> <i>AIHA Laboratory QA Policies, Section 2A.8.11</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.2.9	<p>Personnel conducting independent assessments have sufficient authority, access to work areas, and organizational freedom necessary to observe all activities affecting quality and to report the results of such assessments to laboratory management.</p> <p><i>Quality Systems for Analytical Services, 5.3.1</i> <i>AIHA Laboratory QA Policies, Section 2A.8.11.1</i></p>		
1.2.10	<p>Assessment results are documented, reported to and reviewed by the level of management with authority to affect any necessary corrective actions.</p> <p><i>Quality Systems for Analytical Services, 5.3.2; 5.3.3</i> <i>AIHA Laboratory QA Policies, Section 2A.8.11.1</i></p>		
1.2.11	<p>There has been documented review by management to assess the effectiveness of the quality improvement system.</p> <p><i>Quality Systems for Analytical Services, 5.3.2</i> <i>AIHA Laboratory QA Policies, Section 2.4.8.11.3</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.2.12	The laboratory has established a Non-Conformance System to identify problems, out-of-control events and issues that are not part of scheduled assessments. <i>Quality Systems for Analytical Services, 5.3.5a AIHA Laboratory QA Policies, Section 2A.8.13</i>		
1.2.13	Are all audits, review findings and any corrective actions that arise from them documented? <i>Quality Systems for Analytical Services, 5.3.3 AIHA Laboratory QA Policies, Section 2A.8.11.1</i>		
1.2.14	The laboratory has demonstrated successful participation for a minimum of one year in nationally recognized PE programs. <i>Quality Systems for Analytical Services, 5.3.4b AIHA Laboratory QA Policies, Section 6B</i>		
1.2.15	The laboratory documents the root cause and corrective action for failed PE samples. <i>Quality Systems for Analytical Services, 5.3.4b AIHA Laboratory QA Policies, Section 6B</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.2.16	<p>The laboratory has established a system to identify, document, correct, and prevent quality problems.</p> <p><i>Quality Systems for Analytical Services, 5.3.5a</i> <i>AIHA Laboratory QA Policies, Section 2A.8.10.7</i></p>		
1.2.17	<p>A corrective action process has been implemented which determines:</p> <ul style="list-style-type: none"> • events leading to the adverse condition; • technical activities associated with the problem; • generic implications of the problem; • extent to which similar problems have occurred; • assignment of personnel to corrective action; • documentation of corrective action plan; • effectiveness of corrective actions; • actions taken to preclude recurrence; • review of regulatory requirements; and • client notification. <p><i>Quality Systems for Analytical Services, 5.3.5a2, 4 and 5; 10.1.2b19</i> <i>AIHA Laboratory QA Policies, Section 2A.8.13</i></p>		
1.2.18	<p>The laboratory has a system that tracks corrective actions to completion.</p> <p><i>Quality Systems for Analytical Services, 5.3.5a5</i> <i>AIHA Laboratory QA Policies, Section 2A.8.13</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.2.19	<p>The laboratory maintains:</p> <ul style="list-style-type: none"> a list of typical method detection limits, achieved for water, soil and other matrices commonly analyzed; and procedures for determining limits of detection and frequency of verification. <p><i>Quality Systems for Analytical Services, 5.4a(4)</i> <i>AIHA Laboratory QA Policies, Section 2A.7</i></p>		
1.3	Personnel		
1.3.1	<p>The laboratory maintains records of indoctrination and training in the form of:</p> <ul style="list-style-type: none"> attendance sheets; training logs; personnel training records; and, a description of the training and indoctrination. <p><i>Quality Systems for Analytical Services, 6.2c</i> <i>AIHA Laboratory QA Policies, Section 2A.8.4</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.3.2	<p>Documentation is maintained indicating training in:</p> <ul style="list-style-type: none"> • technical skills; • laboratory analytical methods; • QC procedures; • safety policies; • waste management practices; and, • radiation worker training. <p><i>Quality Systems for Analytical Services, 6.2c(4)v; 6.3; 7.1d; 12.3.4a</i> <i>AIHA Laboratory QA Policies, Section 2A.8.4</i></p>		
1.3.3	<p>The laboratory has a written analyst proficiency evaluation policy that provides a means to gauge and document the continuing competence of experienced individuals, as well as specifying additional training and documentation practices applicable to all personnel.</p> <p><i>Quality Systems for Analytical Services, 6.2b; 12.3.4b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.4</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.3.4	<p>The following personnel criteria have been satisfied:</p> <ul style="list-style-type: none"> management has established personnel qualifications for each position; management has established training requirements for each project person; and, personnel qualifications are reviewed and documented periodically. <p><i>Quality Systems for Analytical Services, 6.2a and c</i> <i>AIHA Laboratory QA Policies, Section 2A.6</i></p>		
1.4	Physical Facilities – Accommodation and Environment		
1.4.1	<p>A copy of the laboratory-specific SOP for glassware is available in the glassware cleaning area. The sample preparation areas are kept clean to avoid contamination or cross-contamination.</p> <p><i>Quality Systems for Analytical Services, 7.2c</i> <i>AIHA Laboratory QA Policies, Sections 2A.5.13 and 2A.3.7</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.5	Equipment and Reference Materials		
1.5.1	<p>A schedule of preventive maintenance activities has been developed and the performance of preventive maintenance is documented.</p> <p><i>Quality Systems for Analytical Services, 8.0e8</i> <i>AIHA Laboratory QA Policies, Section 2A.5.10</i></p>		
1.6	Measurement Traceability and Calibration		
1.6.1	<p>Are all measuring operations and testing equipment having an effect on the accuracy or validity of tests calibrated and/or verified before being put into service and on a continuing basis?</p> <p><i>Quality Systems for Analytical Services, 9.1</i> <i>AIHA Laboratory QA Policies, Section 2A.5</i></p>		
1.6.2	<p>Are measurements made by the labs traceable to national standards of measurement where available?</p> <p><i>Quality Systems for Analytical Services, 9.2a</i> <i>AIHA Laboratory QA Policies, Section 2A.8.7.5</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.6.3	<p>Does the laboratory maintain a record of all calibration certificates that indicate traceability to national standards of measurement and associated uncertainty of measurement and/or statements of compliance with an identified metrological specification?</p> <p><i>Quality Systems for Analytical Services, 9.2b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.7.4</i></p>		
1.6.4	<p>Is there a program of calibration and verification for reference standards?</p> <p><i>Quality Systems for Analytical Services, 9.3b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.7.5</i></p>		
1.6.5	<p>A SOP is in place for reagent and deionized water production which includes (at a minimum):</p> <ul style="list-style-type: none"> • preventative maintenance of water purification equipment; • control criteria; and, • corrective action process for out-of-spec water. <p><i>Quality Systems for Analytical Services, 9.4.1g</i> <i>AIHA Laboratory QA Policies, Section 2.4.8.7.6</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.6.6	The conductivity and/or resistivity of the water from the purification system is monitored daily and the results are recorded in a logbook <i>Quality Systems for Analytical Services, 9.4.1d</i>		
1.6.7	Sample glassware and containers are either designated as disposable or cleaned according to recommended procedures that are listed in the individual Analytical Materials Specifications. <i>Quality Systems for Analytical Services, 9.4.1e</i> <i>AIHA Laboratory QA Policies, Section 2A.5.13</i>		
1.6.8	Procedures are defined for ensuring that balances, refrigerators, ovens, and other laboratory equipment are accurate and that their performance is monitored and documented. <i>Quality Systems for Analytical Services, 9.4.1</i> <i>AIHA Laboratory QA Policies, Section 2A.5.10</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.6.9	Balances are checked each day that they are used and are calibrated at least annually by an independent company or source. The daily balance check shall bracket the range of measurements to be made. <i>Quality Systems for Analytical Services, 9.4.1b and d</i>		
1.6.10	Catastrophic failures of refrigerators and freezer units are addressed in laboratory SOPs. <i>Quality Systems for Analytical Services, 9.4.1a</i>		
1.6.11	Refrigerator temperatures shall be monitored daily. <i>Quality Systems for Analytical Services, 9.4.1d</i>		
1.6.12	Do the SOPs or the test method SOP reference the details or the initial calibration procedures, including calculations, integrations, and acceptance criteria associated statistics? <i>Quality Systems for Analytical Services, 9.4.2.1a</i> <i>AIHA Laboratory QA Policies, Section 2A.7.5</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.6.13	<p>Are sufficient raw data records retained to permit reconstruction of the initial and continuing calibrations using as appropriate, but not limited to:</p> <ul style="list-style-type: none"> • calibration date; • test method; • instrument; • analysis date; • each analyte name; • concentration; • response; and, • calibration curve or response factor. <p><i>Quality Systems for Analytical Services, 9.4.1b, 9.4.2.2c</i> <i>AIHA Laboratory QA Policies, Sections 2A.8.17 and 2A.8.9.2</i></p>		
1.6.14	<p>Is the criteria for the acceptance of an initial calibration established (correlation coefficient or relative percent difference)?</p> <p><i>Quality Systems for Analytical Services, 9.4.2.1e</i> <i>AIHA Laboratory QA Policies, Section 2A.5.5</i></p>		
1.6.15	<p>Is the lowest calibration standard of the initial calibration above the detection limit?</p> <p><i>Quality Systems for Analytical Services, 9.4.2.1f</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.6.16	<p>The initial calibration standards include concentrations that are at or below the regulatory limit/decision level, if known unless these are below the laboratory's demonstrated detection limit?</p> <p><i>Quality Systems for Analytical Services, 9.4.2.1h</i></p>		
1.7	Test Methods and Standard Operating Procedures		
1.7.1	<p>Laboratory activities affecting quality are defined in documented instructions or procedures which are:</p> <ul style="list-style-type: none"> distributed in a controlled manner; periodically reviewed and updated; available to all laboratory personnel; and, retained in the laboratory's archives. <p><i>Quality Systems for Analytical Services, 10.1 a and b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.16</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.7.2	<p>Standard Operating Procedures are in place for (but not limited to) the following areas:</p> <ul style="list-style-type: none"> • sample management; • reagent/standard preparation; • general laboratory techniques; • test methods; • equipment calibration and maintenance; • quality control; • corrective action; • data reduction and validation; • reporting; • records management; and, waste disposal. <p><i>Quality Systems for Analytical Services, 10.1.1e; 10.1.2a; 11.5 AIHA Laboratory QA Policies, Section 2A.8</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.7.3	<p>The laboratory has a procedure delineating the records control system that includes:</p> <ul style="list-style-type: none"> • specifications of items, data, and processes of which records are to be controlled; • requirements for the preparation, review, approval, and maintenance of records to accurately reflect completed work and to fulfill statutory requirements; • requirements and responsibilities for record transmittal, distribution, change, retention, protection preservation, traceability, archival, retrieval, and disposal; • verification that records received are legible and are in agreement with the transmittal document requirements for access to and control of the files; • procedures for the control and client confidentiality accountability of records removed from the storage location; • procedures for filing of supplemental information and disposing of superseded records; • storage of records in a manner approved by the organizations responsible for the records; • replacement, restoration, or substitution of lost or damaged records; and, • procedures for data correction, which include how corrections are to be made and establish who is authorized to change or correct the data. <p><i>Quality Systems for Analytical Services, 5.2d; 10.2b; 12.1; 12.1d; 12.2e</i> <i>AIHA Laboratory QA Policies, Section 2A.8</i></p>		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.7.4	<p>The laboratory has procedures in place to validate non-standardized methods, laboratory designed/developed methods, standardized methods used outside their intended range and amplifications of standardized methods to confirm that the methods are fit for the intended use. The procedures may include:</p> <ul style="list-style-type: none"> • scope; • description of the type of item to be tested or calibrated; • parameters or quantities to be determined; • apparatus, equipment, reference standards and reference materials required; • environmental conditions required and any stabilization period needed; • description of the procedure, including affixing identification marks, handling, transporting, storing and preparing of items, checks to be made before the work is started, checking that the equipment is working properly and, where required, calibrating and adjusting the equipment before each use, method of recording the observations and results, any safety measures to be observed; • criteria and/or requirements for approval/rejection; • data to be recorded and method of analysis and presentation; and, • uncertainty or procedure for estimating uncertainty. <p><i>Quality Systems for Analytical Services, 10.2b</i> <i>AIHA Laboratory QA Policies, Section 2A.7.4</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.7.5	Control methods are accessible to the individual performing the analyses, data reviewers, and the quality assurance staff. <i>Quality Systems for Analytical Services, 10.2b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.10</i>		
1.7.6	Is there a record of a satisfactory demonstration of method capability performed prior to and institution of any test method? <i>Quality Systems for Analytical Services, 10.2.1a</i> <i>AIHA Laboratory QA Policies, Section 2A.7.5</i>		
1.7.7	Where sub-sampling (obtaining sample aliquots from a submitted sample) is carried out as part of the test method, does the laboratory use documented procedures and appropriate techniques to obtain representative sub-samples? <i>Quality Systems for Analytical Services, 10.3</i> <i>AIHA Laboratory QA Policies, Section 2A.7</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.7.8	Does the laboratory establish SOPs to ensure that all quality control measures are reviewed, and evaluated before data is reported? <i>Quality Systems for Analytical Services, 10.4b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.9</i>		
1.7.9	Reagent grade or higher purity chemicals are used. Reagents are checked prior to use and the supporting documentation of the checks shall be filed in a manner that can be easily retrieved. <i>Quality Systems for Analytical Services, 10.5a</i> <i>AIHA Laboratory QA Policies, Section 2A.8.7</i>		
1.8	Sample Handling, Sample Acceptance Policy, and Sample Receipt		
1.8.1	Does the laboratory have a documented system for uniquely identifying the items to be tested, to ensure that there can be no confusion regarding the identity of such items at any time? <i>Quality Systems for Analytical Services, 11.1a</i> <i>AIHA Laboratory QA Policies, Section 2A.8.6.1</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.8.2	<p>The laboratory has procedures in place to address the following:</p> <ul style="list-style-type: none"> • checking sample preservation (pH); • proper containers; • preserving samples when required; • notifying clients of shipping or sample anomalies; • checking holding times and notification of lab personnel of short holding times; • use of fume hoods for opening samples and shipping containers; and, • radiation screening of samples, lab notification and labeling requirements for radioactive samples. <p><i>Quality Systems for Analytical Services, 11.2a, b, c, d and f; 11.3c</i> <i>AIHA Laboratory QA Policies, Section 2A.8.6.4</i></p>		
1.8.3	<p>Sample custodians document anomalies encountered in the sample receiving process.</p> <p><i>Quality Systems for Analytical Services, 11.3c</i> <i>AIHA Laboratory QA Policies, Section 2A.8.6.3</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.8.4	<p>A sample receiving logbook or equivalent system is used to record the chronology of sample entry into the laboratory including time, date, customer, sample identification numbers, etc.</p> <p><i>Quality Systems for Analytical Services, 11.3d</i> <i>AIHA Laboratory QA Policies, Section 2A.9.6.1</i></p>		
1.8.5	<p>When the laboratory receives samples, an internal chain of custody procedure is initiated.</p> <p><i>Quality Systems for Analytical Services, 11.3f</i> <i>AIHA Laboratory QA Policies, Section 2A.8.6.5</i></p>		
1.8.6	<p>Internal custody is maintained until final disposition or return of the sample to the client.</p> <p><i>Quality Systems for Analytical Services, 11.3f</i> <i>AIHA Laboratory QA Policies, Section 2A.8.6.5</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.8.7	<p>A refrigerator storage blank is present for the storage of all volatile organic samples. Specific procedures for assessing the adequacy of these storage blank data and taking action for nonconforming conditions is established. The refrigerator storage blank is analyzed every 14 days when samples are being stored in the laboratory. The data from the analysis of the refrigerator storage blanks is available for review.</p> <p><i>Quality Systems for Analytical Services, 11.4a(2)</i></p>		
1.8.8	<p>Standards and reference materials shall be stored separately from samples and standards protected in a controlled cabinet or refrigerator.</p> <p><i>Quality Systems for Analytical Services, 10.5a; 11.4a(2)</i> <i>AIHA Laboratory QA Policies, Section 2A.8.7.4</i></p>		
1.8.9	<p>The laboratory maintains an indexed sample storage system that facilitates sample retrieval.</p> <p><i>Quality Systems for Analytical Services, 11.4c</i> <i>AIHA Laboratory QA Policies, Section 2A.8.6.5</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.8.10	The laboratory has established, implemented and documented procedures to ensure the sample's radioactivity levels are consistent with the accompanying documentation and that Laboratory regulatory levels are not exceeded. <i>Quality Systems for Analytical Services, 11.4c</i>		
1.9	Records		
1.9.1	Documents are retained for five years or per contract specifications. <i>Quality Systems for Analytical Services, 12.2b</i> <i>AIHA Laboratory QA Policies, Section 2A.8.17</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.9.2	<p>The laboratory maintains hard copy laboratory notebooks that detail:</p> <ul style="list-style-type: none"> the sample bottle preparation and analytical work, including the analyzes being performed; samples being analyzed; procedures used; reading taken; calculations performed; analytical results; and, any observations during analysis. <p><i>Quality Systems for Analytical Services, 12.0; 12.3.1; 12.3.2; 12.3.3</i></p>		
1.9.3	<p>A system is in place to ensure that quality records are legible, accurate, and complete, e.g., independent review of records, logbooks, etc.</p> <p><i>Quality Systems for Analytical Services, 12.1 AIHA Laboratory QA Policies Section 2A.8.9</i></p>		
1.9.4	<p>Corrections to documents that will become quality records are made by drawing a single line through the error, initialing and dating the error, and justifying the correction (if not self-explanatory).</p> <p><i>Quality Systems for Analytical Services, 12.1f AIHA Laboratory QA Policies Section 2A.8.9.3</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.9.5	<p>Records of data and other technical information are maintained in environmentally secure controlled access storage, which shall protect the records from unauthorized access or damage. Alternatively, the laboratory stores duplicate records at a different location.</p> <p><i>Quality Systems for Analytical Services, 12.2e</i> <i>AIHA Laboratory QA Policies Section 2A.8.17.2</i></p>		
1.9.6	<p>Physical or administrative controls exist to ensure that:</p> <ul style="list-style-type: none"> • chain of custody (COC) is not broken during times that laboratory staff are present or not present; • visitor access is controlled by positive administrative controls and strict escort rules developed for all visitors; and, • the facility has controlled entrance and egress points. <p><i>Quality Systems for Analytical Services, 12.4 7.2b</i> <i>AIHA Laboratory QA Policies Section 2A.3.2</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.9.7	<p>Do strip charts, tabular printouts, computer data files, analytical notebooks, and run logs include:</p> <ul style="list-style-type: none"> laboratory sample ID code; date and time of analysis; instrumentation identification and instrument operating conditions/parameters (or reference to such data); analysis type; all manual calculations; and, analyst's or operator's initials/signature <p><i>Quality Systems for Analytical Services, 12.3.3</i></p>		
1.9.8	<p>Are the following administrative records maintained?</p> <ul style="list-style-type: none"> Personnel qualifications, experience and training records; Initial and continuing demonstration of proficiency for each analyst; and, A log of names, initials and signatures for all individuals who are responsible for signing or initiating any laboratory record. <p><i>Quality Systems for Analytical Services, 12.3.4</i> <i>AIHA Laboratory QA Policies Section 2A.6.6</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.9.9	Does the laboratory's legal chain of custody records establish an intact, continuous record of the physical possession, storage and disposal of sample containers, collected sample, sample aliquots, and sample extracts or digestates. <i>Quality Systems for Analytical Services, 12.4.1</i> <i>AIHA Laboratory QA Policies Section 2A.8.6.5</i>		
1.9.10	Do tracking records for legal COC include all information necessary to produce unequivocal, accurate records that document the laboratory activities associated with sample receipt, preparation, analysis and reporting? <i>Quality Systems for Analytical Services, 12.4.2c</i> <i>AIHA Laboratory QA Policies Section 2A.8.6.5</i>		
1.9.11	Is access to all legal samples and sub-samples controlled and documented? <i>Quality Systems for Analytical Services, 12.4.3</i> <i>AIHA Laboratory QA Policies Section 2A.8.6.6</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.9.12	Is transfer of samples, sub-samples, digestates or extracts to another party subject to all of the requirements for legal chain of custody? <i>Quality Systems for Analytical Services, 12.4.4</i> <i>AIHA Laboratory QA Policies Section 2A.8.6.5</i>		
1.9.13	Do records indicate the date of disposal, the nature of disposal (such as sample depleted, sample disposed in hazardous waste facility or sample returned to client), and the name of the individual who performed the task? <i>Quality Systems for Analytical Services, 12.4.5c</i>		
1.10	Laboratory Report Format and Content		
1.10.1	Written procedures are in place for the notification of affected organizations regarding nonconforming items. <i>Quality Systems for Analytical Services, 5.3.5a(5); 13.0e</i> <i>AIHA Laboratory QA Policies Section 2A.8.12.3</i>		
1.10.2	The laboratory has procedures for reviewing and documenting changes made to data after report preparation that ensures traceability of updates. <i>Quality Systems for Analytical Services, 13.0d</i> <i>AIHA Laboratory QA Policies Section 2A.8.9.5</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.11	Subcontracting Analytical Samples		
1.11.1	Does the laboratory have records to indicate that it advised the client in writing of its intention to sub-contract any portion of the testing to another party? <i>Quality Systems for Analytical Services, 14.a and c AIHA Laboratory QA Policies Section 2A.4</i>		
1.12	Outside Support Services and Supplies		
1.12.1	Contracted items and services that have the potential to affect the quality of analytical tests are controlled to ensure conformance with contractual requirements. Such control includes one or more of the following: <ul style="list-style-type: none"> • source evaluation and selection (pre-performance/pre-award survey); • source verification; • audit; and/or, • examination of items or services before use. <i>Quality Systems for Analytical Services, 15.0a and b AIHA Laboratory QA Policies Section 2A.8.8</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.12.2	<p>Procurement system controls makes provision for the following:</p> <ul style="list-style-type: none"> • identify applicable technical and administrative requirements from this Statement of Work for contracted services and items including acceptance criteria; • the process for selecting and qualifying subcontractors; • establishing processes to ensure that qualified subcontractors continue to provide acceptable products and/or services; • accepting purchased items and/or services; • receiving and maintaining procurement records, including evidence of conformance; and, • documenting nonconforming items and services. <p><i>Quality Systems for Analytical Services, 15.0a, b, and c</i> <i>AIHA Laboratory QA Policies Section 2A.8.8</i></p>		
1.12.3	<p>Where there are indications that subcontractors knowingly supplied items or services of substandard quality, this information is forwarded to appropriate management for action.</p> <p><i>Quality Systems for Analytical Services, 15.0c</i> <i>AIHA Laboratory QA Policies Section 2A.8.8</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.13	Complaints		
1.13.1	Does the laboratory have documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities? <i>Quality Systems for Analytical Services, 16</i> <i>AIHA Laboratory QA Policies Section 2A.8.12.2</i>		
1.14	LIMS: If LIMS Audit Module Not Performed		
1.14.1	System backups occur on a regular and published schedule and can be performed by more than one person within an organization. <i>Quality Systems for Analytical Services, 10.6e</i> <i>AIHA Laboratory QA Policies Section 2A.8.17.3</i>		
1.14.2	Computer programs (software) used for instrument performance output, data reduction, and/or for data interpretation shall be validated before use and verified on a regular basis. <i>Quality Systems for Analytical Services, 10.6c</i> <i>AIHA Laboratory QA Policies Section 2A.5.12</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.14.3	<p>Documentation for changes made to data in the LIMS includes:</p> <ul style="list-style-type: none"> the original recorded required documentation; clear evidence that a change was made; the reason for the change; the date of the change; the person who made the change; and, the person who authorized the change. <p><i>Quality Systems for Analytical Services, 10.6e</i></p>		
1.14.4	<p>Software Change Control documentation identifies:</p> <ul style="list-style-type: none"> persons requesting and authorizing software changes; requirements to be met by the change; measures for testing and quality assurance; methods for moving changed versions to the production environment; change request forms/problem reports; and, priority of change requests. <p><i>Quality Systems for Analytical Services, 10.6e</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.14.5	Operating system privileges and file access safeguards are implemented to restrict the use of the LIMS data to users with authorized access. <i>Quality Systems for Analytical Services, 10.6e</i>		
1.14.6	The LIMS is protected from the introduction of computer viruses. <i>Quality Systems for Analytical Services, 10.6e</i>		
1.14.7	A SOP exists for making changes to LIMS Raw Data. <i>Quality Systems for Analytical Services, 10.6e</i>		
1.14.8	A SOP exists for software change control methods that include instructions for requesting, testing, approving, documenting, and implementing changes. <i>Quality Systems for Analytical Services, 10.6e</i>		
1.14.9	Emergency, backup, disaster recovery, and contingency plans exist for the LIMS. <i>Quality Systems for Analytical Services, 10.6e</i>		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.14.10	<p>SOPs exist for:</p> <ul style="list-style-type: none"> • creating electronic data deliverables; • verifying match between electronic and hard copy data; • handling client requested deliverables and modifications. <p><i>Quality Systems for Analytical Services, 10.6e</i></p>		
1.15	AIHA: Additional Industrial Hygiene QA Criteria		
1.15.1	<p>The QAP is reviewed and approved by management at least annually.</p> <p><i>AIHA Laboratory QA Policies, Sect. 2.7.1</i></p>		
1.15.2	<p>If the laboratory analyzes for lead, it demonstrates successful participation in the AIHA Environmental Lead Proficiency Testing (ELPAT).</p> <p><i>AIHA Laboratory QA Policies, Sect. 2C</i></p>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.15.3	If the laboratory analyzes for bulk asbestos, it demonstrates successful participation in the National Voluntary Laboratory Accreditation Program (NVLAP) Bulk Asbestos Accreditation Program or the AIHA Bulk Asbestos Program. <i>AIHA Laboratory QA Policies, Sect. 2B</i>		
1.15.4	Management and supervisory personnel possess a BS or BA in applicable physical or biological science and 5 years directly related experience. <i>AIHA Laboratory QA Policies, Sect. 2A.6</i>		
1.15.5	Written documentation is available to support qualification of staff consisting of a listing of personnel, their assignments, responsibilities, degrees of education and years of applicable experience. <i>AIHA Laboratory QA Policies, Sect. 2.5.6</i>		
1.15.6	All analysts and technicians have a minimum of 30 calendar days of hands-on experience conducting analyses in an industrial hygiene laboratory before initiation of independent work on customer samples. <i>AIHA Laboratory QA Policies, Sect. B.3.2.3</i>		

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.15.7	At least quarterly, the QA Manager provides reports to laboratory management regarding quality assurance problems and corrective and preventive actions. <i>AIHA Laboratory QA Policies, Sect. 2A.8.15</i>		
1.15.8	Standard Operating Procedures are in place for (but not limited to) the following areas: <ul style="list-style-type: none"> • analytical tests; • sample tracking and COC (from receipt to disposition); • sample preparation (including subsampling); • sample storage and security; • proper sample disposition; • prevention of sample contamination; • facility security; • data reduction, verification, and reporting; • acceptance criteria (e.g., QC limits, calibration, etc.); • document control; • data packages review prior to submittal; • shipment of deliverables; • records disposition; • preparation and traceability of standards; • catastrophic failure of a refrigerator, freezer unit; • glassware cleaning; • equipment maintenance; and, • qualification of personnel and training. <i>AIHA Laboratory QA Policies, Sect. 2.7.16</i>		

Status Key: A = Acceptable, U = Unacceptable, NA = Not Applicable, F = Finding, O = Observation

Audit ID: _____

Auditor: _____

Item	Line of Inquiry	Status	Summary of Observations/Objective Evidence Reviewed/Audit Notes
1.15.9	Annually or when there is a change in methodology or instrumentation, reporting limits are verified by a statistically valid MDL study. <i>AIHA Laboratory QA Policies, Sect. B.4.3.3)</i>		
1.15.10	The laboratory is currently accredited by AIHA. <i>AIHA Laboratory QA Policies Section 2A.1</i>		
1.15.11	If the laboratory analyzes for environmental lead, it possesses an ELLAP accreditation.		